

## **REMARKS**

Claims 1-16 were submitted for examination. The Examiner has repeatedly referred to Claims 1-19 in the office action, but we interpret that as being a typographical error. Likewise, in part 10 of the office action summary, the Examiner has not indicated whether the filed drawings are accepted or objected to. We also interpret this to be the result of a typographical error, and deem that the drawings filed have been accepted by the Examiner. We would appreciate the Examiner's confirmation of our above interpretations of what appear to be typographical errors are correct.

Claims 1-16 stand rejected under 35 USC §112, paragraph 2, as being indefinite. The Examiner alleges that the phrase "convertible to a homogeneous emulsion which simulates an anticoagulated whole blood sample" is unclear. The Examiner further alleges that the term "liquid" is inadequate to define a layer in the process and that the process must require beads or the like. The Examiner alleges that "beads" are missing from the claims. The Examiner further states that "it would appear" that an "essential physical property" of the liquid components of the control must be claimed.

The Examiner's comments regarding Claims 4 and 5 are well taken and have been addressed in the above amendments to the claims.

Claims 1-16 stand rejected under 35 USC §112, first paragraph as being non-enabled by the specification as filed. Specific grounds of this rejection are that: 1) the specification, as filed does not describe how the mixture is converted to a homogeneous emulsion; and 2) and it is unclear "how exactly the blood is simulated, and to what effect".

We will address the above-noted §112 rejections herein below. Before addressing the above noted rejections, we note that the Examiner has used the phrase "would appear" at least eight different times in the office action. The Examiner, however, has not bothered to pinpoint how the "would appear" comments support his §112 rejections. Additionally, the Examiner has made repeated references as to how Applicants "should" claim their invention. These comments by the Examiner are not supported by the patent statute. 35 USC §112, para. 2, explicitly states that the applicant may claim the subject matter which the "applicant regards as his invention", not what a patent examiner regards as the invention.

### **THE §112, PARAGRAPH 2, REJECTIONS:**

The 35 USC 112 requirement of definiteness of claim language is essentially a requirement

for precision and definiteness of claim language so that the claims make clear what subject matter they encompass, and thus what the patent precludes others from doing. See: In re Spiller, 182 USPQ 614 (CCPA 1974); and In re Conley, 180 USPQ 454 (CCPA 1974). Claims cannot be read in a vacuum, but must be read in light of application disclosure and teachings of prior art; second paragraph of 35 USC 112 requires merely that claims set forth and circumscribe particular area with reasonable degree of precision and particularity, and that applicants claim that which they consider to be their invention. See: Ex parte Calhoun and Bennett, 195 USPQ 455 (PTO Bd. App. 1976); and In re Johnson and Farnham, 194 USPQ 187 (CCPA 1977).

From the aforesaid case law, it will be noted that claims cannot be said to be vague and indefinite if the specification and the prior art enable one to understand what the claims encompass. It is quite clear that the claims *per se* do not have to be as limited as the Examiner demands in the office action in order to satisfy the requirements of §112, second paragraph, of the statute. We will now specifically address the Examiner's grounds for formulating these rejections. We note that all of the claims have been rejected without being individually analyzed by the Examiner. The Examiner is thus erroneously treating the claims as though they are all equivalent to each other.

1) First of all, the Examiner alleges that it is unclear what exactly is required to simulate blood. This allegation indicates to Applicants that the Examiner has not carefully reviewed the specification, or the numerous prior art patents that were noted in the specification and incorporated into this application in their entirety.

It is common knowledge that blood consists generally of four different components. One component is erythrocytes, or red cells; a second component is white cells; a third component is platelets; and the fourth component is plasma.

It is also common knowledge that the white cells include lymphocytes, monocytes and granulocytes which have different cell sizes.

It is also common knowledge that the platelets are cell fragments. It is also common knowledge that the plasma is a fluid in which all of the formed components of blood are suspended.

It is also common knowledge that when blood is centrifuged, it will separate out gravimetrically into its different component layers due to the difference in the density, or specific gravity, of the different components of blood, and also due to the different sizes of the cells which make up the white cell component.

It is also common knowledge that the erythrocytes are the highest density component of blood and will gravitate to the bottom of a centrifuged blood sample, followed by the white cell layer, which will settle out by cell size above the erythrocyte layer, followed by the platelet layer which will settle into a layer above the white cell layer, and finally followed by the plasma layer which will settle out above the platelet layer. The Examiner's attention is directed to U.S. Patent No. 4,027,660 for a thorough discussion of the aforesaid. This patent was referred to in the specification of this application and incorporated into this application in its entirety. Apparently, the Examiner has not reviewed this patent. The entire QBC technology, which is referred to in the specification, is based on the aforesaid "common knowledge" regarding the composition of blood. The fallacy in the Examiner's allegation is that one skilled in the art would not know what the composition of blood is.

Thus, in order to simulate blood, the simulation should include a first component that mimics the erythrocytes in density; a second component that mimics the white cells and platelets in different sizes and in density; and a third component that mimics the plasma in density. The Examiner is invited to simply read the first full paragraph of page 3 of the specification. This paragraph clearly sets forth the general ground rules for how to simulate a blood sample in practicing this invention. It is respectfully submitted that the qualities of the layers and how and in what way it is that blood is being simulated is clearly set forth in the specification of this application. The Examiner's allegation to the contrary is thus clearly erroneous, and is completely unsupported by the Examiner with any facts.

2) The Examiner states that "It would appear" that "liquid" is inadequate to define a layer in "the process" and that the "process" must require beads or the like. The Examiner goes on to allege that "It would appear that essential elements, e.g., **beads are missing** from the claims." (emphasis added). What does the Examiner think that "particulates" and "microspheres" are? We also note that the claims in this application are not directed to a "process", they are directed to a "mixture". We have noted above that the Examiner has repeatedly used the phrase "it would appear" as grounds for rejecting claims in the office action. In Ex parte Levy, 17 USPQ2d 1461 (US PTO Bd. Pat. App. & Int. 1990), the Board held that the initial burden of establishing a *prima facie* basis to deny patentability rests upon the examiner. See also In re Carleton, 202 USPQ 165 (CCPA 1979); and In re Piasecki, 223 USPQ 785 (Fed. Cir. 1984). This burden can only be discharged by establishing a factual basis for the finding of non-patentability. Examiner's conjecture or conclusionary assertions do not provide the necessary factual basis. The Examiner's grounds for rejecting the claims in this application which are based on an allegation that "it would appear" are nothing more than unsupported conjecture or conclusionary assertions, and do not provide a factual basis for the stated rejections. This rejection suggests that the

Examiner has not read the claims, and does not understand his burden of proof and how to discharge it.

Regarding the Examiner's allegation that the physical properties of the liquid components of the mixture must be claimed in order to satisfy the requirements of §112, paragraph 2 is clearly erroneous. In order to satisfy the requirements of the clarity requirements of the statute, the physical properties of the liquid components of the mixture must be clarified by the combination of the specification and prior art, which they are. The physical properties of the liquid components of the mixture have been discussed above.

These grounds for rejecting the claims are thus clearly erroneous and is completely unsupported with any facts.

3) The Examiner states that "It is unclear what scope of 'liquid' or 'component' is in the instant claims as it relates to the desired utility.". Is the Examiner alleging here that one skilled in the art would not know the meaning of the words "liquid" or "component"? The relevance of this comment is unclear to the undersigned. Please clarify.

4) As noted above, the Examiner's comments regarding Claims 4 and 5 are accurate, and they have been rendered moot by the amendments to these claims.

#### **THE §112, PARAGRAPH 1. REJECTIONS:**

Once again, all of the claims have been rejected without bothering to analyze the subject matter of each of the individual claims. This is an improper approach to rejecting claims. The specific grounds for rejecting the claims are addressed hereinafter. The PTO's burden of proof in calling into question the enablement of applicant's disclosure requires the PTO to advance acceptable reasoning inconsistent with specification's enablement In re Strahilevitz, 212 USPQ 561 (CCPA, 1982).

1) The Examiner alleges that the specification does not describe how the claimed mixture is converted into a homogenous emulsion. The Examiner also alleges that the use of liquid layers is not enabled by the specification.

Regarding the first allegation, the Examiner's attention is directed to lines 1 and 2 on page 9 of the specification. It is clearly stated that the mixture can be converted to an emulsion by simply inverting or shaking a tube containing the mixture.

Regarding the second allegation, the Examiner's attention is directed to the paragraph bridging pages 5 and 6 of the specification. Clearly, there are a number of suitable liquids

identified in this paragraph for use in the mixture of this invention.

With all due respect, it is submitted that the §112, paragraph 1 rejections addressed above seem to indicate that the Examiner has not bothered to read the specification here. These rejections should be reconsidered and withdrawn.

2) In the first paragraph on page 6 of the Office Action, the Examiner repeats, *verbatim*, the contents of the third full paragraph on page 4 of the office action, which was one ground for rejecting the claims under §112, paragraph 2. As noted before in this response, beads or their equivalents are explicitly recited in all of the claims in this application, and the nature of the beads is clearly enabled by the specification. The Examiner's attention is directed to the contents of pages 6-8 of the specification regarding the beads. The essential physical property of the liquid components of the mixture do not have to be explicitly recited in the claims so long as they are identified in the specification and in the prior art, which they clearly are, so that one skilled in the art, contrary to the Examiner's allegation, would know how to create the liquid components of the mixture.

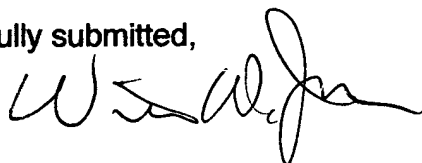
This rejection is a four-peat "would appear" rejection and is completely baseless. This rejection should thus be reconsidered and withdrawn. As noted above, Examiner's factually baseless rejections which are based on "would appear" conjecture do not discharge the Examiner's burden of proof in providing a valid rejection.

3) Summing up the grounds for the rejection set forth in the second full paragraph on page 6 of the office action, the Examiner states that "Applicant should claim the invention in such a way that it is enabled by the specification and make it clear how the claims are supported by the specification.". The specification makes it quite clear exactly how blood is simulated by the mixture of this invention, as discussed above; it is also quite clear that the specification identifies several liquids and components that would enable one skilled in the art to practice the invention which is claimed in this application.

The Examiner's grounds for rejecting all of the claims in this application under §112, paragraph 1 are completely groundless, and they should be reconsidered and withdrawn.

In view of the above-noted amendments to the claims, and the arguments advanced above, it is respectfully submitted that this application is presently in condition for allowance. Early notice to that effect is courteously requested.

Respectfully submitted,

A handwritten signature in black ink, appearing to read "W. S. Alfa", is written over the text "Respectfully submitted,".

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